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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,312

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Francis Navarro

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EXAMINER

WACHTEL, EMILY L

ART UNIT

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4111

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,312	Applicant(s) NAVARRO ET AL.	
	Examiner EMILY WACHTEL	Art Unit 4111	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6 and 10-15 is/are rejected.
- 7) ☒ Claim(s) 4 and 7-9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>August 31, 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species A claims 1-15 in the reply filed on November 27, 2007 is acknowledged.
2. Claims 16-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 27, 2007.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the ratchet mechanism in claim 14 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

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be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “19” has been used to designate both slits and the membrane. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because of the following informalities:

Page 4 line 8 --of this catheter-- does not make sense

Throughout specification reference number 3 is referred to as “support base”, reservoir” “sleeve-shaped support base”, and “sleeve” which is found to be unclear.

6. Claim 4 is objected to because of the following informalities:

--that the base-- should be --the base--

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-3, 5-6, and 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, the applicant recites “a second chamber for accommodation of a base of the catheter *and at least one external tube in fluid communication with the catheter*” (emphasis added). It is unclear whether the second chamber is for accommodation of an external tube or if the external tube is an additional feature of the device. For purposes of examination the claim has been interpreted in such a manner as to read that the second chamber has the intended use of accommodating a base of a catheter and the intended use of accommodating an external tube where the tube is in fluid communication with the catheter.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-2, 5, 10, and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Landuyt (U.S. Patent 6,387,076 B1).

With regards to claim 1, Landuyt teaches **a device for fixing a catheter to a patient, comprising a housing** (Figure 1- base plate 1 is taken to be functionally equivalent to the

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housing), **a lid closing the housing** (Figure 1 - lid 2, Col. 2 line 27), **a base integral to the housing and surrounding the housing, for fixation of the housing to skin of the patient** (The base is taken to be the underside/lower portion of base plate 1 which is integral to the housing and contains adhesive for securing the base plate to the patient, Col. 3 lines 6-9 see enclosed figure), **wherein the housing comprises first and second chambers which communicate with each other** (Figure 1, chamber 1 is taken to be encompassed by opening 12 and enlarged portion 14, Col. 3 lines 34-46, the second chamber is taken to be encompassed by channel 11 specifically locating region 16, Col. 3 lines 43-44 see enclosed reference figure 1), **the first chamber including an opening for passage of the catheter implanted in the patient** (Figure 1 -passage 13 Col. 3 lines 38-40), **and a second chamber for accommodation of a base of the catheter and at least one external tube in fluid communication with the catheter.** (The chamber defined as the second chamber would be capable of accommodating a base of the catheter and an external tube - see enclosed reference figure 1).

With regards to claim 2, Landuyt teaches **the housing is flat and has a relatively small height with respect to the base** (As seen in Figure 1, housing base 1 has a small height with regards to the overall bottom base), **the first chamber and the second chamber are approximately co-planar** (The chambers as defined in claim 1 can be seen to be approximately co-planar see enclosed reference figure 1), **and the lid comprises, on an internal face, two pads which penetrate into the second chamber** (Figure 1 -lid 2 comprises gripping means 34 comprising teeth 35 which are taken to be functionally equivalent to the comprised pads, Col. 2 lines 66-67 -Col. 3 lines 1-3), **when the lid is closed, and rest, respectively, against respective lateral faces of the base of the catheter, holding the base of the catheter bilaterally with**

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respect to a flat bottom of the second chamber (The teeth 35 are capable of holding the base of the catheter with respect to the flat bottom, Col. 3 lines 32-36), **when fixed to the skin of the patient.**

With regard to claim 5, Landuyt teaches an adhesive ring around the circumference of the base plate (Col. 3 lines 9-10). This would effectively encompass a membrane on the bottom of the first chamber, as the bottom of the first chamber is taken to be the portion encompassed in the circumference of the lower portion of the base. This also allows for the passage of the base of the catheter.

With regard to claim 10, Landuyt teaches the second chamber opens directly into the first chamber (Figure 1, see chambers as defined in enclosed figure Reference 1) and includes a hollow part having a shape cooperating (chamber 2 has a hollow portion) with an identical hollow part defined between the two pads (two pads are taken to be outer two teeth 35 of figure 1, the hollow shape of the chamber *cooperates* with the space between these two teeth) of the lid to form, when the lid is closed, a recess which matches the base of the catheter for retaining the base in the housing (the catheter base would be retained within the housing).

With regard to claim 14, applicant has stated that ratchet mechanisms are known within themselves (Page 13 lines 20-21). Therefore, it is a showing that it would have been obvious to a person of ordinary skill to use a ratchet mechanism as a lid closure.

With regard to claim 15, Landuyt teaches the device being stuck to the skin using adhesive (Col. 3 lines 17-18), taken to be functionally equivalent to the colloid in claim 15.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as set forth in paragraph 9 as applied to claim 2 above, and further in view of Brimhall (U.S. Patent 5,306,253).

With regard to claim 3, Landuyt does not teach two wings on the base of the catheter. However, Brimhall teaches wings used for catheter insertion so that the catheter can be properly gripped (Col. 1 lines 59-63 Figure 1 wings 14 and 14'). It would have been obvious to one of ordinary skill in the art to use a winged catheter base because the wings would allow for better gripping and stability during insertion into the body. Further the device in Landuyt will be capable of holding the base of the catheter against the bottom of the second chamber.

13. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references in paragraph 9 as applied to claim 5 above, and further in view of Kornerup (U.S. Patent 5,685,859).

With regard to claim 6, Landuyt does not teach that the membrane comprises slits extending from an edge which delimits the orifice. However, Kornerup teaches a membrane which more closely surrounds the area in which a tube is inserted into the body and shows a slit

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(Figure 1 slit 2, Col. 5 line 16) which delimits the device. It would have been obvious to a person of ordinary skill in the art that in the case where the membrane would more fully cover the aperture and the area in which the tube is inserted that slits would be used because this would allow space to accommodate the insertion of the tube and would allow room for tubes of various sizes.

14. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references set forth in paragraph 9 as applied to claim 5 above, and further in view of Bierman (U.S. Patent 6,428,516).

With regard to claims 11 and 12, Landuyt doesn't teach an adhesive including a sheet of flexible material molded with the housing or two holdfasts in the shape of human ears. However, Beirman teaches flexible anchor pad 32 (Figure 1) for securing the retainer to the patient's skin (Col. 7 lines 9-10). This pad is not disclosed to be molded with the housing however, it would have been obvious to a person of ordinary skill in the art to use a one piece construction and make the parts integral (In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965)). Further, Beirman shows the pad to be in the shape of two human ears so as to provide greater stability and adhesion to the patient's skin. It would have been obvious to a person of ordinary skill in the art to attach the device in Landuyt using an adhesive pad molded to the housing the shape of two human ears because it would provide greater stability.

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15. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references set forth in paragraph 14 as applied to claim 12 above, and further in view of Wright et al. (US 2004/0167475 A1).

With regard to claim 13, Landuyt does not disclose the housing comprising four support holdfasts in the form of human ears. However, Wright et al. teaches a securement device which has a shape that can be taken to be in the shape of four human ears (Page 4 [0045] Figure 11 base 120). And further, that various shapes can be made as desired. It would have been obvious to a person of ordinary skill in the art to use four ear shaped holdfasts as opposed to two as it is within the skill of one in the art to duplicate parts and such has no patentable significance (In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)) and further the four holdfasts could provide a support base which better secures the base to the patient as it would provide for increased arrangement possibilities for adhering to the patient's skin, having a greater number of independently movable holdfasts, which could better conform to a variety of locations on the patient.

Allowable Subject Matter

16. Claims 4 and 7-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Prior art reference Landuyt (U.S. Patent 6,387,076 B1) does not teach, nor is there motivation to combine so as to meet, the limitation of two oblique lateral faces which are perpendicular to the bottom of the second chamber and converge towards the first chamber as in claim 4, nor the limitation of external pads which penetrate the first chamber as in claim 7.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are pertinent as catheter anchoring systems: Annis (U.S. Patent 4,659,329), Bierman (U.S. Patents 5,693,032, 6,447,485, and 6,491,664), and Bierman et al. (U.S. Patents 6,770,055 and 6,572,588).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY WACHTEL whose telephone number is (571)270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on (571) 272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Supervisory Patent Examiner, Art Unit 4111